

### REMARKS

This communication responds to the Office Action of February 20, 2009, in which claims 1-35 are pending, and claims 1-20, 33 and 34 have been withdrawn. The Applicants respectfully assert that the claims are allowable at least for the reasons discussed below. Reconsideration and allowance are thus respectfully requested.

#### Claim Rejections Under 35 U.S.C. §102

Claims 21, 22, 24, 26-29 and 32 were rejected under 35 U.S.C. § 102(e) as anticipated by Shepard (US 2004/0078078). This rejection is traversed at least for the following reasons.

The present claims are directed to a spinal implant having a smooth surfaced cylindrical bore for receiving an implant insertion instrument. The bore of the spinal implant is sized and configured to closely match an insertion portion of the implant insertion instrument such that the instrument may be used to rotate or otherwise finely manipulate the implant in the plane of the disc space to a desired orientation from an initial improper insertion orientation. Impact forces on the handle of the insertion instrument torque the instrument and implant in the desired direction with minimum stress concentration on the implant in the bore to minimize damage to the bone that might otherwise occur in the presence of such stress concentrations. *US2004, 0098128, Abstract, paras. [0060] and [0061]*.

The Examiner rejects the pending claims over Shepard, a reference that does not suggest an implant receiving bore much less an implant receiving bore sized and configured to closely match an insertion portion of the implant insertion instrument. Indeed, Shepard has nothing to do with the disclosure of the present application other than to be a fusion implant. Further, even in that regard, Shepard teaches an implant fundamentally different from the implant of the present claims.

Shepard is directed to a two piece allograft cervical fusion block for use in orthopedic surgical procedures, including one component member of load bearing material, such as cortical bone, and another component member of cancellous bone. *Shepard, para. [0021]*. A dovetailed recess of the cancellous component member receives a dovetailed projection of the cortical component member such that the two component members are fixed together. *Shepard, para. [0061]*. Pins are mounted in both component members to provide additional stability. *Shepard, Abstract*.

The Examiner asserts that Shepard discloses: “a bore (40 or 42) ... configured to receive an instrument (elements 40, 42 would be fully capable of receiving an instrument that may displace force over a relatively wide area of the bore).” *Present Office Action*, p. 2. The Examiner has mischaracterized the disclosure of the Shepard reference. As a preliminary matter, the element numbers referenced by the Examiner are pins. Pins cannot be interpreted as bores. The Applicants assume that the Examiner intended to reference the bores 44 and 46 that receive the pins 40 and 42. Those bores are provided expressly for receiving the pins referenced by the Examiner to stabilize the implant:

If desired, pins 40 and 42 can be inserted in through going bores 44 and 46 cut through both component members 12 and 30 to increase stability to the graft. The pins 40 and 42 are preferably constructed of cortical bone but can be constructed from any biocompatible material having the necessary strength requirements including metals, plastics compositions and the like and are friction fit in the respective bores 44 and 46.

*Shepard, para. [0063].*

Claim 21, as amended, recites a spinal bone implant comprising, in part, “[a] body having an outer peripheral surface and an instrument-receiving bore formed in the outer peripheral surface at the anterior end, ... the bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore.” At no point does Shepard give any discussion of an implant-receiving bore, much less an implant-receiving bore having a diameter and length wherein the diameter and length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument.

Not only are the bores 44, 46 of Shepard per se not instrument receiving bores, they could not be used as instrument receiving bores without compromising the integrity of the Shepard implant. An implant manufactured in accordance with Shepard having bores *without* pins inserted therethrough has compromised stability. The very purpose of the bores is to receive pins to stabilize the implant. As discussed in para. [0030] of the present application, a surgeon can use the instrument-receiving bores to receive an instrument to “torque and rotate or otherwise reorient the implant to its preferred location.” Inserting an instrument through the bores of Shepard, where the pins necessarily would not be placed to stabilize the implant, and then

torquing the instrument would impart torque to an already compromised implant. The Applicants respectfully submit that torquing a compromised implant would be contrary to the teachings of Shepard.

Indeed, Shepard specifically discusses ways to reorient the implant, ways that do not compromise the integrity of the implant:

The cortical front is mated to the cancerous [sic] component with the crosspiece inner planar surface being adjacent the cancerous [sic] component. The cortical or load bearing component bears not only a compressive load but also serves as an impaction surface. Thus, the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancerous [sic] portion of the graft.

*Shepard*, para. [0063]. As is observed from the foregoing, Shepard teaches that a surgeon may orient the bone grafts by tapping the grafts with a suitable instrument, thus eliminating any need for a instrument receiving bore. Such tapping for placement is typical in the art, as discussed at paras. [0026]-[0027] of the present application.

Further, even if the bores 44, 46 somehow could be used for receiving an implant insertion instrument, they do not have a diameter and a length wherein the diameter and the length substantially match a diameter and a length of an implant engaging portion of an implant insertion instrument. Indeed, the present application describes that it is not sufficient to merely provide bores:

Apertures and bores and recesses normally used for insertion instruments are thus not satisfactory. This is because of the lack of match of a randomly selected instrument to implant recesses or bores used for insertion of the implant.

*US 2004/0098129*, para. [0061]. Given the lack of any teaching by Shepard that the bores 44, 46 could be used to receive an implant insertion instrument, there is no basis for concluding that inserting an instrument into such bores would rise beyond the level of inserting a randomly selected instrument into a bore not suited for receiving such instrument.

Shepard teaches inserting stabilizing pins through bores to limit axial and lateral movement. Shepard further teaches that reorientation of the implant may be achieved by tapping on the implant. The Examiner attempts to interpret Shepard in a manner that would provide an implant with bores without stabilizing pins, thus in a compromised state of stability as per the

very teachings of Shepard, and then insert an instrument through such bores to torque, rotate, or otherwise reorient the compromised implant – notwithstanding Shepard’s specific disclosure of manners to reorient the implant that do not torque an implant having compromised stability.

There is no teaching or suggestion whatsoever in Shepard of an implant receiving bore “having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore,” as recited by claim 21. The Applicants thus submit that claim 21 is allowable over Shepard. Each of the remaining claims depends either directly or indirectly from Shepard and is allowable for the reasons discussed with respect to claim 21. New Claim 36 recites a spinal bone implant having an instrument-receiving bore as described with respect to claim 21 and further having a central opening in communication with the inferior and superior surfaces of the body. New Claim 37 recites a spinal bone implant having an instrument-receiving bore as described with respect to claim 21 and further being formed of a monolithic piece of cortical bone. The Applicants respectfully submit that these claims are allowable at least for the reasons discussed with respect to claim 21. Allowance of the claims is thus respectfully requested.

*Claim Rejections Under 35 U.S.C. §103*

*Rejection over Shepard in view of McKay*

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of McKay (US 6,261,586). This rejection is traversed at least for the following reasons.

In framing the rejection of the present claims, the Examiner conceded that Shepard does not teach a central opening with a blind bore. The Examiner attempts to use McKay as teaching a bone graft that may be used in the spine and having a central opening and a blind bore. The Examiner explains that the central opening can be packed with an osteogenic composition to stimulate osteoinduction and that it thus would have been obvious to one of ordinary skill in the art at the time the invention was made to have a central opening and a blind bore, where the central opening can be packed with an osteogenic composition to stimulate osteoinduction.

McKay teaches a bone graft substitute including a composition of natural selectively deactivated bone material that has been processed to remove associated non-collagenous bone

proteins. *McKay, Abstract*. McKay teaches a cortical bone graft having a chamber to receive osteoinductive material because the cortical bone graft generally is not osteoinductive:

Preferably, the load bearing member is a bone graft obtained from the diaphysis of a long bone having a medullary canal which forms the chamber 25 ... The chamber 25 can be packed with an osteogenic composition to stimulate osteoinduction.

*McKay, Col. 11, ll. 4-8*.

In contrast, Shepard purports to teach a composite implant comprising a structural portion (the cortical component) and an osteoinductive portion (the cancellous component). At the time of the invention of Shepard, Shepard was aware of implants formed of cortical long bones, such as McKay. Shepard identified shortcomings of such implants and developed the Shepard implant to overcome such problems:

Cortical spacers are often shaped from cortical long bones, which are primarily found in the lower limbs and include, for example, femur, fibular, and the tibia bones. However, these long bones make up only a fraction of the available bone source. Cancellous bone, because of its superior osteoinductive properties, would be desirable to use [sic] in the spinal implant. However, the lower mechanical strength of cancellous [sic] bones prohibits its use in many surgical applications.

*Shepard, para. [0011]*. Indeed, the specific need purportedly solved by Shepard is to combine the strength of cortical bone with the osteoinductivity of cancellous bone:

Consequently, there is a need for an implant which should have with [sic] a load bearing compressive strength of 1000 to 5000 Newtons with a compressive load to be a minimum of 3000 Newtons as a safety factor. There is also a need to have a portion of cancellous [sic] bone immediately adjacent to the load bearing cortical zone to permit rapid ingrowth of a patient's own new bone with the cancellous bone forming the major part of the implant.

*Shepard para. [0020]*. Accordingly, Shepard already purports to solve the problem that the Examiner posits as the basis for modifying the implant of Shepard with the teachings of McKay. Given that Shepard specifically claims that its non-cortical portion imparts osteoinductivity, there would be no motivation to further provide a central opening through Shepard to receive osteoinductive material.

Further, there is no basis for concluding that Shepard could be provided with a central opening and still be structurally sound. As discussed, Shepard teaches a two part implant wherein each of the component parts have a respective dove-tail portions for mating. As noted in the portion of Shepard reproduced above, the cancellous component forms the major part of the Shepard implant. A central opening would have to be provided through the cortical structural component, a relatively small component in the Shepard implant. It is not clear how a bore could be provided through the structural component and the implant still be suitable for its intended purpose.

The Applicants thus submit that neither Shepard nor McKay, alone or in combination, teach the invention as claimed. The Applicants further submit that Shepard and McKay are not combinable as suggested by the Examiner. Reconsideration and allowance of claim 23 are thus respectfully requested.

*Rejection over Shepard in view of Henry*

Claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of Henry (US 5,766,252). This rejection is traversed at least for the following reasons.

As discussed above, Shepard does not disclose the invention of claim 21. Henry does not remedy the fundamental teaching deficiencies of Shepard. Henry teaches an interbody spinal prosthetic implant including a rigid member having vertically opposed load-bearing surfaces and sides spaced laterally apart. *Henry, Col. 3, ll. 8-14*. The Examiner cites Henry as teaching a spinal implant which has a central opening in communication with an anterior end bore, where the central opening can promote fusion by being filled with bone graft material, and the bore can be used to engage an insertion tool.

As discussed with respect to the combination of Shepard and McKay, the Applicants respectfully submit that it would not be obvious or even possible to modify the Shepard reference with a central opening that can be filled with bone graft material. As discussed with respect to the rejection over Shepard, a mere hole that may possibly receive an instrument is not a "bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore," as recited by claim 21.

The Applicants thus submit that neither Shepard nor Henry, alone or in combination, teaches the invention of the present claims. Reconsideration and allowance of claim 25 are thus respectfully requested.

*Rejection over Shepard in view of Lahille*

Claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of Lahille et al (US 5,544,191). This rejection is traversed at least for the following reasons.

As discussed above, Shepard does not disclose the invention of claim 21. Lahille does not remedy the fundamental teaching deficiencies of Shepard. Lahille teaches an intersomatic cage which includes two parallel branches for insertion into vertebral bodies, a linking portion for linking ends of the branches, and a means for annularly spreading ends of the branches after insertion. *Lahille, Col. 1, ll. 54-61*. The Examiner cites Lahille as teaching a spinal implant which has roughened superior and inferior surfaces for the purpose of anchoring the prosthesis in place. Even if Lahille were to disclose such surfaces, the combination of Shepard and Lahille still would not teach the invention of the present claims.

Neither Shepard nor Lahille, alone or in combination, teach an implant comprising a body having, among other things, a “bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore.” Reconsideration and allowance of claim 30 are thus respectfully requested.

*Rejection over Shepard in view of Boyle*

Claims 31 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of Boyle et al. (US 2002/0026242). This rejection is traversed at least for the following reasons.

As discussed above, Shepard does not disclose the invention of claim 21. Boyle does not remedy the fundamental teaching deficiencies of Shepard. Boyle teaches a ramp-shaped intervertebral implant including a body having an opening extending from upper and lower surfaces thereof. *Boyle, para. [0038]*. The Examiner cites Boyle as teaching an intervertebral

implant which is made from a section of cortical bone from the diaphysis of a long bone. Even if Boyle were to disclose such surfaces, the combination of Shepard and Boyle still would not teach the invention of the present claims. Further, as discussed with respect to the rejection over Shepard in view of McKay, Shepard was aware of implants formed from a section of cortical bone. Shepard intended to address deficiencies of such implants. Accordingly, the Applicants submit that it would not be obvious to modify the implant of Shepard with the teachings of Boyle.

Neither Shepard nor Boyle, alone or in combination, teach an implant comprising a body having, among other things, a "bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore." Reconsideration and allowance of claims 31 and 25 are thus respectfully requested.

Conclusion

This response is being submitted on or before August 20, 2009, with the required fee for a 3-month extension of time, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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